UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

Subject: EPA Reg. # 63310-8; Rhizopon AA Water Soluble Tablets

TO: Cynthia Giles-Parker PM # 22. Attn.: Leonard Cole
Herbicide-Fungicide Branch
Registration Division (7505C)

FROM: David L. Ritter, Toxicologist D 162 2-8-94
Precautionary Review Section
Registration Support Branch
Registration Division (7505W)

THRU:: Thomas C. Ellwanger, Jr., Section Head
Precautionary Review Section
Registration Support Branch
Registration Division (7505W)
Mary Waller
for T.E.
3/4/94

Registrant: Hortus USA Corp.

Action Requested:

Review Delayed Contact Dermal Sensitization study.

PRS Response:

No label or transmittal document accompany the submission.

The dermal sensitization study has been reviewed and the DER is appended. It is rate CORE Supplementary because no positive control data were included. The study may be upgraded upon receipt and evaluation of positive control data performed in this laboratory. Such data must have been obtained within six months of the date the present study was completed.

Enclosure in jacket

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DATA EVALUATION RECORD DERMAL SENSITIZATION TESTING (§81-6)

Product Manager (PM): 22 EPA Reg. No.: 63310-8

Reviewer: David L. Ritter, Toxicologist DLR 9-3-93

MRID No.: 424491-01

Testing Laboratory: MB Research Laboratories, Inc.
PO Box 178
Spinnerstown PA 18968

Title Of Report: Delayed Contact Dermal Sensitization (Buehler Method)

Date of Report: 7/27/92

Lab. No.: MB 92-1615 F

Author(s): Daniel R. Cerven, MS

Quality Assurance (40 CFR, Section 160.12): Study Director signed QA statement. This is at variance with 40 CFR 160.35(a).

Species: Hartley Albino Guinea Pigs

Sex: 15 M
Wt.: 289 - 343 gm

Source: Ace Animals (no address)

Test Material: Rhizopon Water Soluble Tablets

Dosage: 0.5 gm

Summary:

CORE Classification: Supplementary. No positive control data included in the report.

Procedure:

Modified Buehler assay[1].

Standard laboratory animal husbandry and GLP procedures were followed.

Test animals were weighed initially and at termination.

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[1]Ritz, H.L and E. V. Buehler. Current Concepts in Cutaneous Toxicity. p. 28. Academic Press, NY, 1980.

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Animals were prepared by clipping the dorsal area clear of fur one day prior to exposure.

Screen Procedure: Not reported.

Induction Phase:

Undiluted Test Article, moistened with distilled water was applied under a 25 mm Hilltop Chamber and secured by a rubber dental dam wrapped with adhesive tape. Animals were restrained for ca. six hours. The dressings were then removed and the application sites were evaluated for dermal reaction at 24 and 48 hours. The procedure was repeated at weekly intervals for two more treatments, for a total of three weekly treatments.

Challenge Phase:

Two weeks after the third induction treatment all animals received 0.5 gm undiluted Test Article at a virgin application site.

Results:

Animals showed normal weight gains.

Induction Phase: No dermal irritancy response was reported for any animal.

Challenge Phase: No dermal irritancy response was reported for any animal.

Positive Controls: Not reported.

Conclusions:

No dermal irritancy response was reported for any application period, and no positive control data were included in the report although the author indicated that such data were available.

Without the positive control data we are unable to verify that the test system is predicting sensitizing potential in the guinea pig.

The study is classified CORE Supplementary. This could be upgraded if data from the positive control study was made available. Positive control data must be within 6 months of test group data. MW

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ACUTE TOX ONE-LINER

1. PC CODE: 046701; IBA

2. CURRENT DATE: 9/7/93

3. TEST MATERIAL: Rhizopon AA Water Soluble Tablets

4. EPA Reg. #: 63310-8

Study/Species/Lab/ Study#/Date	MRID No.	Results	Tox. Cat.	Core Grade
Dermal Sens. MB Res. /MB 92-1615F/7-27-92	424491-01	No results; no historical positive control group	----	S

Core Grade Key:

G = Guideline
M = Minimum
S = Supplementary